DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 19, 2014

Devon Medical Products
Mr. Steve Xu
Regulatory Affairs Specialist
1100 First Avenue, Suite 202
King of Prussia, Pennsylvania 19406

Re: K140634
Trade/Device Name: extriCARE 2400 NPWT System with extriCARE 2400 NPWT pump and extriCARE NPWT Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 20, 2014
Received: August 21, 2014

Dear Mr. Xu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140634

Device Name
extriCARE 2400 NPWT System with extriCARE 2400 NPWT pump and extriCARE NPWT Foam Dressing Kit

Indications for Use *(Describe)*
The extriCARE® NPWT foam kit is intended to be used in conjunction with the extriCARE® 2400 NPWT pump. The extriCARE® 2400 Negative Pressure Wound Therapy System is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The extriCARE Negative Pressure Wound Therapy System is indicated for the following wound types: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510K Summary

Submitter:

Devon Medical Products

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Phone: 610.757.4103

Fax: 610.930.4035

Contact Person: Ruth Wu, CCO

Date Prepared: September 19, 2014

Device:

Common Names: Negative Pressure Wound Therapy Foam Dressing Kit

Negative Pressure Wound Therapy Pump

Proprietary Name: extriCARE NPWT Foam Dressing Kit

extriCARE 2400 NPWT Pump

Regulatory Class: II

Product Code: OMP

Common or Usual Name: Powered suction pump

Classification: 21 CFR 878.4780

Predicate Devices:

The extriCARE 2400 Negative Pressure Wound Therapy Pump and Foam Dressing Kit are equivalent to the following:

Predicate Device	Manufacturer	510(k) Number
extriCARE 2400	Devon Medical Products	K110078
extriCARE 3600	Devon Medical Products	K132225
Renasys NPWT Foam Dressing	Smith & Nephew	K082211
A4-XLR8 Foam Dressing	Genadyne Biotechnologies, Inc.	K092992

Device Description

Premarket notification device:

extriCARE® NPWT Foam Dressing Kit

extriCARE® 2400 NPWT Pump

The extriCARE® Negative Pressure Wound Therapy (NPWT) System consists of extriCARE® NPWT Pump, canister, connection tubing, and dressing kit. In operation, the dressing is attached to an extriCARE® Negative Pressure Wound Therapy pump via the tubing. The pump is used to provide the negative pressure to the system. Pressure and mode selections are digitally programmable.

The extriCARE NPWT foam dressing kit is a new accessory to the NPWT system. The foam dressing kit is designed to be an alternative solution to the bandage dressing kit in the original system. The foam dressing kit consists one of each of the following: polyurethane foam, transparent film drape, paper ruler, Suction Bell with connecting (drainage) tube and clamp. The single-use foam dressing kit is packed in Paper/poly peel pouch bag, which is sterilized using ETO. The foam is used to pack the wound.

The extriCARE® NPWT foam dressing kit can be sold alone or as a part of the extriCARE 2400 system.

The associated accessories include:

- Large foam dressing kit
- Medium foam dressing kit
- Small foam dressing kit

Intended Use:

The extriCARE® Negative Pressure Wound Therapy (NPWT) foam kit is intended to be used in conjunction with the extriCARE® 2400 NPWT pump. The extriCARE® 2400 NPWT system is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The extriCARE Negative Pressure Wound Therapy System is indicated for the following wound types: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Technological Characteristics Comparison:

The subject extriCARE 2400 NPWT pump is an update of the cleared extriCARE 2400 NPWT pump (K110078).Below is a table of comparison for the technological characteristics of the NPWT pump against the predicate device:

Predicate	Subject extriCARE 2400 Pump	Predicate extriCARE 2400 Pump	extriCARE 3600 Pump
Indication	-	SE	S
Components	-	S	S
Material	-	S	S
Principle of Operation	-	S	S
Flow Rate	-	S	N

Sterilization	-	N/A	N/A
Biocompatibility	-	N/A	N/A
Software	-	N	N
Pressure Range (mmHg)	40-140	20-200	40-200
Blockage alarm (Y/N)	Y	N	Y

The extriCARE 3600 NPWT pump has a higher flow rate than the subject extriCARE 2400 NPWT pump. The subject extriCARE 2400 NPWT pump has different software than the predicate extriCARE 2400 NPWT pump (K110078) and extriCARE 3600 NPWT pump.

Below is a table of comparison for the technological characteristics of the foam dressing against the predicate device:

Predicate	extriCARE 2400	extriCARE 3600 Foam Dressing	RENASYS -F NPWT Foam Dressing Kit	A4-XL R8 Foam Dressing
Indication	N/A	S	SE	SE
Single Use	N/A	S	S	S
Components	N/A	S	S	S
Material	N/A	S	SE	SE
Biocompatibility	N/A	S	SE	SE
Sterilization	N/A	S	SE	SE
Principle of Operation	N/A	S	S	S

- S: same - SE: substantial equivalent N: Different

The foam dressing used in this submission is the exact same foam dressing used in the K132225 submission. The K110078 extriCARE NPWT system does not consist foam dressing.

Performance Tests

To verify that the device design met its function and performance requirements, aged samples of the device underwent the following tests.

- extriCARE 2400 Performance Test with extriCARE Foam Dressing
- Pressure accuracy Test
- Pressure maintenance over time Test
- Extended continuous exudates removal Test

The conclusions drawn from the performance tests demonstrate that the device is performing as intended, and is safe and effective.

Biocompatibility

Biocompatibility is not applicable to the extriCARE 2400 NPWT pump.

The biocompatibility evaluation for the extriCARE NPWT Foam Dressing Kit was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Sterilization and Shelf-Life

Sterilization is not applicable to the extriCARE 2400 NPWT pump.

Sterilization has been done for the extriCARE NPWT Foam Dressing Kit. Aged samples are used for sterilization and testing.

Electrical Safety and Electromagnetic Compatibility (EMC)

EMC is not applicable to extriCARE NPWT Foam Dressing Kit.

Electrical safety and EMC testing for extriCARE 2400 NPWT pump is omitted because the electrical parts are the same as its predicate cleared in K110078.

Software Verification and Validation

Software verification and validation were conducted and documentation was provided. The software of subject device has changed substantially comparing to its predicate in K110078. The software was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury to the patient or operator.

Animal Study and Clinical Study

No animal study or clinical study was conducted.

Statement of Substantial Equivalence

The extriCARE NPWT System with Foam Dressing Kit is substantially equivalent in technology, function, operating parameters, and intended use to predicate devices that are currently commercially available and in distribution, and does not raise any new questions of safety or effectiveness.